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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/661,693	09/14/2000	Sathasivan Indiran Pather	CIMA 3.0-030 CONT II	2096

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LERNER, DAVID, LITTENBERG,  
KRUMHOLZ & MENTLIK  
600 SOUTH AVENUE WEST  
WESTFIELD, NJ 07090

EXAMINER

DEWLITTY, ROBERT M

ART UNIT	PAPER NUMBER
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1616

DATE MAILED: 11/27/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/661,693

Applicant(s)

PATHER ET AL.

Examiner

Robert M DeWitty

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 22 October 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 22-36 and 83-87 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 22-36 and 83-87 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_ 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

Claims 22-36 and 83-87 are pending in the instant application.

Acknowledgement is made of Applicant's RCE filed 10/22/02.

#### ***Claim Rejections - 35 USC § 112***

1. Claim 22 and 84 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicant has included the limitation that the effervescent couple is present in an amount between about 5% and about 80%. However, the instant application does not <sup>teach</sup> this range. The instant application teaches a range of between about 5% and about 95%, and preferably between 30% and about 80% (instant application, page 4, lines 20-24).

Applicant has also amended claim 22 to included the limitation that the couple is "greater than the amount necessary for tablet disintegration". However, the instant specification does not contain any reference to what amount this may be or where this limitation may be found.

Appropriate correction is required.

#### ***Claim Rejections - 35 USC § 102***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

2. Claims 22-24, 26-36, and 83-87 are rejected under 35 U.S.C. 102(b) as being anticipated by DiSanto (U.S. Pat. No. 6,117,912).

DiSanto teaches the administration of selegiline (active ingredient) buccally or sublingually. At example 3, column 6, DiSanto teaches an effervescent selegiline tablet for sublingual or buccal administration. The amount of sodium bicarbonate (the effervescent) present in example 3 is more than 61% (at 185 mg/dose). As the selegiline HCl is the active ingredient used, the active ingredient (as a HCl compound) is able to affect pH.

### ***Claim Rejections - 35 USC § 103***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. Claims 22 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over DiSanto, further in view of Tsuk et al. (U.S. Pat. No. 3,972,995).

As stated above, DiSanto teaches an effervescent selegiline tablet for sublingual or buccal administration. However, DiSanto does not teach using a bioadhesive.

Tsuk relates to dosage forms for buccal administration of a drug. In use, the dosage form is applied to the inside of the oral cavity, such that the drug is exposed to a small area of the oral mucosa while isolating the drug from the remainder of the oral

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cavity, thus rapidly achieving high drug blood levels (col. 1, line 65-col. 2, line 7 and col. 2, lines 40-48).

Based on the art available at the time the invention was made, one with ordinary skill in the art would have known of an effervescent tablet containing a medicament for sublingual or buccal administration and bioadhesive. Motivation to utilize a bioadhesive within such effervescent tablet would have arisen out of desire to obtain rapid high drug blood levels.

### ***Response to Arguments***

4. Applicant's arguments filed have been fully considered but they are not persuasive.

Applicant asserts that the term "effervescent agent" is synonymous with "effervescent couple" and therefore it is improper to consider only one component (as shown in the prior art) to determine the amount of effervescent in the composition. Whereas "effervescent couple" is referred to in the instant specification, it is not evident that the "effervescent couple" refers to an agent containing multiple components. The specification does state the reaction is most often the result of an acid source and carbon source, but it is the examiner's position that this is a preferred reaction and not a necessary one. Therefore, the effervescent couple can be one agent or multiple agents. As such, the teachings of DiSanto anticipate claim 22, and the rejection is maintained.

Applicant also asserts that DiSanto does not teach modification of the amount of effervescent. However, DiSanto clearly teaches that Sodium bicarbonate is useful in an amount of 185mg. It is understood by the examiner that this means sodium bicarbonate is 61% of the formulation, and thus falls within Applicant's stated range.

Regarding Applicant's attempt to accentuate the difference between the prior art and the instant application (namely the amendment of claim 22 to include the limitation of the couple present in an amount greater than the amount necessary for tablet disintegration), DiSanto teaches the use of sodium bicarbonate in an amount within the range of the instant invention. Thus, it is the examiner's position that DiSanto teaches using an effervescent in an amount greater than the amount necessary for disintegration.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert M DeWitty whose telephone number is 703-308-2411. The examiner can normally be reached on 9:00am - 5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jose Dees can be reached on 703-308-4527. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-7924 for regular communications and 703-308-7924 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.


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RMD

November 19, 2002

  
JOSE C. DEES  
SUPERVISORY PATENT EXAMINER  
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